UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,152	11/12/2003	Steven T. Luebbers	7016US01	7581

25755 7590 09/01/2006

ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
625 CLEVELAND AVENUE
COLUMBUS, OH 43215-1724

EXAMINER	
PRATT, HELEN F	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,152	LUEBBERS, STEVEN T.	
	Examiner	Art Unit	
	Helen F. Pratt	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girsh (5,204,134) or Cope et al. (5,480,872) or Hill et al. (5,382,439) in view of Lien et al. (US 2004/0062849).

Girsh discloses a process of making a hypoallergenic milk by sterilizing a liquid nutritional formula aseptically containing Vitamin D and hydrolyzed protein. The short chain polypeptides are obtained by appropriate hydrolysis. The short chain polypeptide has a molecular weight of from 1 to 5 kDa (abstract and col. 5, lines 15-30, col. 9, lines 5-15, col. 10, lines 15-18). Applicants' specification on page 11, 1st paragraph, discloses that hydrolyzed proteins can be various weights, e. g. 2000 to 5000 Daltons. It is not known what molecular weight applicants' proteins would have been if hydrolyzed to at least 20%. Also, Girsh discloses the use of amino acids and short chain polypeptides derived from hydrolysates (col. 10, lines 25-25). Therefore, absent a showing to the contrary, it is seen that Girsh discloses protein hydrolysates as disclosed above which have the claimed degree of hydrolyzation and it would have been obvious to use such with vitamin D in an especially packaged process in aseptic containers.

Cope discloses that it is known to use soy protein hydrolysates having a DH of from 14 to 17 and in the use of particles having a molecular weight of from 1,500-500 Daltons in a composition containing vitamin D3 (abstract, col. 15, lines 5-44, in particularly lines 5-10). Claim 1 differs from the reference in having a DH of at least 20%. However, the reference discloses about 14-17 DH and the claim says "at least about 20%". Nothing is seen at this time that a DH of 17 would not have produced a product similar or the same as applicants. Cope also discloses that aseptic methods can be used to treat the composition (col. 16, lines 54-60). Therefore, it would have been obvious to use a hydrolyzed protein at near the claimed range and vitamin D in a process for aseptic composition.

Hill et al. disclose a process of improving the stability of V-D in liquid nutritional products using hydrolyzed protein and vitamin C (abstract). The composition is heat treated aseptically (col. 3, lines 15-22). Claim 1 differs from the reference in the use of hydrolyzed protein to the claimed degree. Nothing is seen that the protein is not hydrolyzed to the claimed degree especially as even amino acids are used (col. 4, lines 29-34). Therefore, it would have been obvious to use hydrolyzed protein and amino acids in the claimed process as shown by Hill.

The above references do not show the exact degree of protein hydrolysis. However, Lien et al. disclose that it is known to use isolated soy protein with a DH of from 5-20%. Therefore, it would have been obvious to use a known DH of protein in the processes of the above references in order to improve the digestibility of the protein (abstract and para. 0011, 0035).

Nothing new is seen as in claims 2 and 3, in the use of plastic packages and resealable unidose packages, which are commonly in use as in, milk containers and baby formula containers. Therefore, it would have been obvious to use known types of packages in the claimed process.

Claims 4 and 5 further require more hydrolysis of the protein. However, as it is known to hydrolyze protein, it would have been obvious to hydrolyze to whatever degree was required depending on the purpose of the product. Cope discloses the use of vitamin C in the composition (col. 14, lines 48-51) and Girsh in col. 7, lines 5-10.

Claim 7 further requires that the V-D have a degradation rate reduction from 20-40% and claim 8 from 25-35%. However, nothing is seen that the process of the above references would not have produced such a degradation rate. Therefore, it would have been obvious to produce degradation rates within or near the claimed range as shown by the references.

Girsh discloses a liquid infant formula as in claim 9 (col. 10, lines 30-35).

No further heat sterilization is seen in the above references as in claim 10.

Certainly, Girsh discloses as in claim 11 that the formula is free from intact proteins, as his process uses amino acid and polypeptides (col. 14, lines 14-16).

The limitations of claims 12-30 have been disclosed above and are obvious for those reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hp 8-29-06

HELEN PRATT
PRIMARY EXAMINER